



1645

Docket No: B0192.70051US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Frank KARLSEN  
Serial No.: 10/500,832  
Confirmation No.: 8927  
Int'l Filing Date: January 7, 2003  
Title: METHOD FOR DETECTING HUMAN PAPILLOMAVIRUS mRNA  
  
Examiner: Not yet assigned  
Art Unit: 1645

**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 20<sup>th</sup> day of April, 2005.

  
June Watson

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ PTO-1449 Form with cited references
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

No fee is enclosed. If a fee is necessary, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By:   
John R. Van Amsterdam, Reg. No. 40,212  
Wolf, Greenfield & Sacks, P.C.  
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Telephone: (617) 646-8000

Docket No. B0192.70051US00  
Date: April 20, 2005  
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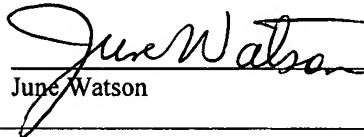
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

**International Search Report from PCT Application No. PCT/GB03/00034.**

**International Search Report from PCT Application No. PCT/GB03/00030.**

**UK Patent Office Search Report for GB 0200239.2**

**PART III: Explanation of Non-English Language References and Remarks Concerning Other Information Cited**

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

**PART IV: Remarks**

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

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Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

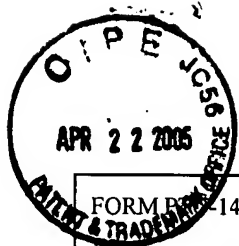
By: 

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DOCKET NO. B0192.70051US00

FORM PTO 1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/500,832		DOCKET NO.: B0192.70051US00	
				INT'L. FILING DATE: 01/07/03		CONFIRMATION NO.: 8927	
				APPLICANT: Frank Karlsen			
				GROUP ART UNIT: 1645		EXAMINER: Not yet assigned	
Sheet	1	of	2				

**U.S. PATENT DOCUMENTS**

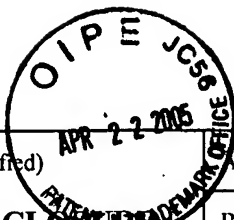
Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	5,639,871	A	Bauer, Heidi M., et al.	06/17/1997

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	EP	0 662 518	A2	AMOCO Corp.	07-12-1995	
	B2	EP	0 373 352	A2	Behringwerke Aktiengesellschaft	06-20-1990	N
	B3	WO	03/057927	A2	Norchip AS	07-17-2003	
	B4	WO	03/057914	A2	Norchip AS	07-17-2003	
	B5	WO	01/73135	A2	Biosearch International Pty. Ltd	11-04-2001	
	B6	WO	99/29890	A2	Digene Corporation	06-17-1999	
	B7	WO	94/26934	A2	Baxter Diagnostics, Inc.	11-24-1994	
	B8	WO	90/02821	A1	Cetus Corp.	03-22-1990	
	B9	WO	02/08460	A2	Norchip AS	01-31-2002	
	B10	WO	00/00638	A2	Deursen Petrus Bernardus Hugo	01-06-2000	
	B11	WO	91/08312	A2	Gene-Trak Systems	06-13-1991	
	B12	EP	0 402 132	A2	Takara Shuzo Co., Ltd.	12-12-1990	
	B13	EP	0 243 221	A1	Institut Pasteur	10-28-1987	
	B14	EP	0 774 518	A2	Gen Probe Inc.	05-21-1997	

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	SMITS, H.L., et al. "Application of the NASBA nucleic acid amplification method for the detection of human papillomavirus type 16 E6-E7 transcripts," Journal of Virological Methods, Amsterdam, NL, Vol. 54, No. 1, 1995, pgs. 75-81	
	C2	CORNELISSEN, M.T. E. et al., "Uniformity of the splicing pattern of the E6/E7 transcripts in human papillomavirus type 16-transformed human fibroblasts, human cervical premalignant lesions and carcinomas," Journal of General Virology, Society for General Microbiology, Reading, GB, Vol. 71, No. Part 5, (May 1, 1990), pgs. 1243-1246	



FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 10/500,832		DOCKET NO.: B0192.70051US00			
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				GROUP ART UNIT: 1645		EXAMINER: Not yet assigned			
Sheet	2	of	2						

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C3	MCNICOL, Patricia et al., "Expression of human papillomavirus type 16 E6-E7 open reading frame varies quantitatively in biopsy tissue from different grades of cervical intraepithelial neoplasia,," Journal of Clinical Microbiology, Vol. 33, No. 5, 1995, pgs 1169-1173	
	C4	JEON, Saewha, et al., "Integration of human papillomavirus type 16 DNA into the human genome leads to increased stability of E6 and E7 mRNAs: Implications for cervical carcinogenesis," Proceedings of the National Academy of Sciences of the U.S., Vol. 92, No. 5, 1995, pgs 1654-1658	
	C5	LEONE, et al., "Molecular beacon probes combined with amplification by NASBA enable homogeneous, real-time detection of RNA," Nucleic Acids Research, 1998, Vol. 26, No. 9, pgs. 2150-2155	
	C6	WALBOOMERS, Jan M.M., et al., "Human papillomavirus is a necessary cause of invasive cervical cancer worldwide," Journal of Pathology, J. Pathol. 189: pgs. 12-19 (1999)	
	C7	BOSCH, F. Xavier, et al., "Prevalence of Human papillomavirus in cervical cancer: a worldwide perspective," Journal of the National Cancer Institute, Vol. 87, No. 11, June 7, 1995, pgs. 796-802	
	C8	KATO, Satoshi, et al., "Detection of human papillomaviruses in cervical neoplasias using multiple sets of generic polymerase chain reaction primers," Gynecologic Oncology, Vol. 81, No. 1, (April, 2001) pgs. 47-52	
	C9	IWASAWA, Akihiko, et al., "Human papillomavirus DNA in uterine cervix squamous cell carcinoma and adenocarcinoma detected by polymerase chain reaction," American Cancer Society, Vol. 77, No. 11, (6/1/96), pgs. 2275-2279	
	C10	DOEBERITZ, M., "New molecular tools for efficient screening of cervical cancer," Vol. 17, 2001, pgs. 123-128	
	C11	LANHAM, S., et al., "HPV detection and measurement of HPV-16, telomerase, and survivin transcripts in colposcopy clinic patients," J. Clin. Pathol., Vol. 54, 2001, pgs. 304-308	
	C12	COUTLEE, F., et al., "Detection of transcripts of human papillomaviruses 16 and 18 in Cancer-derived cell lines and cervical biopsies by enzyme immunoassay for DNA-RNA hybrids following solution hybridization," J. Clin. Micro, Vol. 29, 1991, pgs. 968-974	
	C13	DATABASE, "HPV sequence Database, 'Online! 'Los Alamos National Laboratory; 09-1997, Los Alamos National Laboratory; "Human papilloma viruses 1997 compendium," pgs. E6-10 - E6-24	
	C14	WU SHUENN-Jue L., et al. "Detection of dengue viral RNA using a nucleic acid sequence-based amplification assay," Journal of Clinical Microbiology, Vol. 39, No. 8, August 2001	

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office has waived the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications.]